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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,536	03/25/2004	Masahiko Kurauchi	US-169	5925

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EXAMINER

JOHNSON, JASON H

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,536

Applicant(s)

KURAUCHI ET AL.

Examiner

Jason H. Johnsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 14 is/are allowed.
- 6) ☐ Claim(s) 1-5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

S.D

DETAILED ACTION

The rejections regarding claim 6 is withdrawn in light of the cancellation of this claim. Additionally, the rejection of claim 14 has been withdrawn in light of the amendment submitted on 05/26/05. New rejections on claims 1-5, and 7 are set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunio Tsuji (JP 8-27008) and Poluektova et al ("Immunostimulating properties of the complexes of inosine derivatives," Int. J. Immunopharmac., Vol. 17, No. 11, pp. 941-947, 1995). Claim 1 is drawn to an inosine L-arginine salt. Claim 2 further limits the compound of claim 1, wherein the inosine and L-arginine are present in substantially equimolar amounts. Claim 5 is drawn to a composition comprising the inosine-L-arginine salt of claim 1. Claim 7 further limits the

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composition of claim 6 (erroneously dependent on a cancelled claim), wherein said inosine and said L-arginine are present in substantially equimolar amounts. Claim 7 is examined as if it depends from the only preceding composition claim, claim 5.

Kunio Tsuji discloses nucleoside salts, and presents an example with inosine as the nucleoside (paragraph 15-17). Tsuji does not explicitly disclose any nucleoside salts, as argued by applicant, nor does Tsuji teach making any nucleoside salts. However, Tsuji teaches a compound formed by a nucleoside, such as inosine, with a physiologically compatible salt, and gives several examples, one being arginine (paragraph 16). Furthermore, Poluektova teaches a compound and composition comprising inosine with and L-arginine salt—L-arginine butyrate, in substantially equimolar amounts, as well as a method of making said compound (see page 941 and 942).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the above taught compound and composition having the above-cited references before him. Kunio Tsuji teaches various nucleoside salts, including the combination of inosine as the nucleoside and arginine as the salt. Poluektova et al. teach a specific compound consisting of inosine with an L-arginine salt. The prior art's suggestion of combinations of inosine and L-arginine combined as salt render the instant compounds and compositions *prima facie* obvious.

2. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunio Tsuji (JP 8-27008) and Poluektova et al ("Immunostimulating properties of the complexes of inosine derivatives," *Int. J. Immunopharmac.*, Vol. 17, No. 11, pp. 941-947, 1995).

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Claim 3 is drawn to an inosine L-arginine salt produced by the process of dissolving the two products in water, in substantially equimolar amounts, and then drying the dissolution product. Claim 4 teaches the additional step of adding anhydrous ethanol prior to drying. Claim 14 teaches a method of making an inosine L-arginine salt comprising dissolving in water inosine and L-arginine in substantially equimolar amounts, adding the product of the first step to anhydrous ethanol, and drying the product of the second step to obtain the salt.

Claims 3 and 4 fail to further limit the inosine L-arginine compound and composition and are therefore, rejected for the same reason claims 1 and 2 are rejected. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. (MPEP 2113). “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Objections

Claim 7 is objected to because of the following informalities: Claim 7 erroneously depends from a cancelled claim. Appropriate correction is required.

Conclusion

The limitations taught by Claim 14-the method of making an inosine-L-arginine salt by dissolving in water inosine and L-arginine in substantially equimolar amounts; and adding the

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product of this step to anhydrous ethanol; and drying the product of the anhydrous ethanol step to obtain the salt-- are not taught or fairly suggested by the prior art.

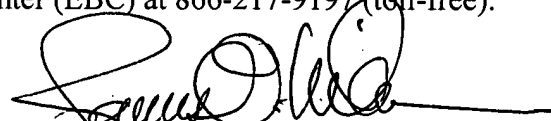
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason H. Johnsen** whose telephone number is **571-272-3106**.

The examiner can normally be reached on Mon-Friday, 8:30-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason H. Johnsen
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623